Reverse Engineering and Rapid Prototyping Techniques
to Innovate Prosthesis Socket Design

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ABSTRACT

The paper presents an innovative approach totally based on digital data to optimize lower limb socket prosthesis design. This approach is based on a stump’s detailed geometric model and provides a substitute to plaster cast obtained through the traditional manual methodology with a physical model, realized with Rapid Prototyping technologies; this physical model will be used for the socket lamination. The paper discusses a methodology to reconstruct a 3D geometric model of the stump able to describe with high accuracy and detail the complete structure subdivided into bones, soft tissues, muscular masses and dermis. Some different technologies are used for stump acquisition: non contact laser technique for external geometry, CT and MRI imaging technologies for the internal structure, the first one dedicated to bones geometrical model, the last for soft tissues and muscles. We discuss problems related to 3D geometric reconstruction: the patient and stump positioning for the different acquisitions, markers’ definition on the stump to identify landmarks, alignment’s strategies for the different digital models, in order to define a protocol procedure with a requested accuracy for socket’s realization. Some case-studies illustrate the methodology and the results obtained.

Keywords: 3D geometrical model, reverse engineering, rapid prototyping, human body scanning, medical imaging, lower limb prosthesis.

1. INTRODUCTION

The paper introduces some important aspects of an innovative methodology which authors are developing, to customize design process of lower limb prosthesis. An important part of prosthesis is the socket; it must adapt to the patient’s morphology because it is the interface between the stump and the prosthesis. Socket’s customization is essential in order to obtain the best adaptability to the patient’s body, guaranteeing a high functional degree and comfort. Until now lower limb prosthesis have been designed and manufactured with handicraft methods, leaving out an adequate functionality and however depending on the skills of the orthopaedic technician, who must find the shape of the residual limb, since this is the first step in the socket design of a lower limb prosthesis.

The current design process (Fig.1) is based on a double-step realization of the stump’s plaster cast; in the first step, the technician has to mould manually some plaster bandages pressing on the stump. After the bandages’ solidification, the obtained “mould” is used for the final stump plaster cast. During the first moulding, the technician manipulates the stump, producing deformations especially on fleshy parts, and such a configuration could be different from the resting configuration.

Aim of our activity is to propose a computer aided design methodology, based on digital models and numerical simulations in order to obtain the physical mock-up of the stump on which socket’s lamination could be made, applied to the trans-tibial prosthesis case. The proposed methodology has three relevant technical features: first, the reconstruction of a 3D geometrical model of the residual limb, then the numerical simulation of the structural behaviour of the stump, and finally the rapid manufacture of a physical mock-up of the stump.

In this paper we discuss the first aspect that is the reconstruction of the 3D digital model of the stump, which replaces plaster cast. For this aim we have used, compared and integrated:

- Reverse Engineering technologies, for the external surface limb acquisition;
- X-ray technique, such as Computer Tomography (CT), for the inner structure acquisition, divided into components (bone structure, muscle tissue, soft tissue and dermis);

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• medical imaging technique, such as Magnetic Resonance Imaging (MRI), used for complete residual limb acquisition that could be a CT substitute since it is a non-invasive operating technique.

All these three methods are used to reconstruct the geometric model of the external limb surface, CT and MRI are used also for the bone reconstruction; with the integration between external surface and bone models it is possible to obtain a complete digital model of the residual limb. This model is essential to permit simulations, that repeat both technician’s manipulations and stresses between stump and socket during patient’ movement.

The expected result from simulation activities is the lower limb morphology adapted to realize a physical mock-up with Rapid Manufacturing techniques\(^2\); using this prototype it is possible to manufacture directly the structure of the socket, made of composite material.

The paper describes the procedure adopted to acquire morphology with the indicated methods, the characteristic of the digital models reconstructed, the merging between inner and external models to obtain the complete digital model.

### 2. METHODS ADOPTED ON STUMP’S MEASUREMENT

Problems related to stump’s measurement have been analyzed in various studies. This practise is crucial in the design process of prosthesis and it needs to be repeated several times during the patient’s life; the lower limb, in fact, is subject to continuous morphological changes, both in the short and in the long term and these changes require, when any significant variation occurs, the realization of a new socket.

Actually, the stump is measured manually, with obvious problems of accuracy depending on the instruments used\(^3\), on the operators’ skills\(^4,5\), on the measurement conditions and on the status of the patient’s stump. Therefore several measurement protocols have been developed; they define anthropometric standard dimensions which can be used in order to define significant markers on the limb (an example on Fig. 2), usually in correspondence with the articulations. These markers are used as reference for the reconstruction of biomedical images, in FEM simulations and for human gait analysis\(^6,7\). In the examined test of trans-tibial amputee, important parameters are stump length (from the under patella support to tibia apex) and femoral condyle position: these points are the best fitted under the skin, so they are invested with less variations of shape and volume of the skin than the other stump parts.
In some research, the Reverse Engineering techniques have been employed in order to estimate shape and dimensions of the human body or its parts; there are also studies about bone prosthesis applications, usually concerning measurements on physical prototypes of bones artificial joints, and of the residual limb plaster cast. On residual limb prosthesis, studies have detailed residual limb analysis with imaging technologies such as CT, MRI and ultrasound system, concerning limb shape and volume changes and the effects of socket’s permanent wearing. In the last years, there have been residual limb analysis concerning integration system between medical imaging and CAD socket design, as it is yet developed in dental prosthesis and tissue engineering.

3. A METHODOLOGY TO RECONSTRUCT GEOMETRIC MODEL

This paper deals with the problem of the definition of the best methodology, at the state of the art, for the limb geometrical model reconstruction; for this purpose, technological solutions described in scientific literature previously reviewed have been taken into account and compared. The acquisition of the external geometry of the stump and its inner parts has been considered; for the limb surface we reconstructed the digital models coming from the laser scanning and both medical imaging of CT and MRI. Bones are reconstructed from both CT and MRI, having a chance between them; in fact, it is known that MRI imaging cannot be used when patient has some metallic support into his bone after amputation. These two diagnostic systems have different application field though similar: CT is widely employed to reveal bones’ fractures or problems, while MRI permits to detail with care muscular and cartilaginous diseases.

In order to guarantee the comparison among the digital models acquired by using the different methods, it is necessary to define some operative conditions for geometry acquisition; in particular:
- a patient’s posture taken as reference. This posture should be as much as possible similar to the one adopted at the present time for the manual acquisition, which has been taken as reference;
- identification of fixed markers on the stump which will be used in order to verify the obtained dimensional parameters.

For patient’s posture during the acquisition phase, we defined a configuration which reproduces lower residual limb’s position during manual measurements for chalk manufacturing. We realized a device which supports the residual leg with an angle of \( \cong 45^\circ \) between femoral bone and tibiae, with the patient lying down on the bed, and with the stump totally relaxed and without stresses or compressions on the masses. We realized this supporting device trying to reduce constraints on deformable stump parts, even these directly connected with standard laying position of CT/MRI scanners.
which causes relevant deformations of flashy parts at stump’s apex and gastrocnemio muscle. These deformations may produce problems for socket’s comfort and functionality if not carefully considered into the design process. In order to identify the markers, lead shot with diameter $\Phi = 2\text{mm}$ have been used: they can be seen both through the laser scanner and through CT, while in the MRI case some round tablets of vitamin E with diameter $\Phi = 3\text{mm}$ have been employed.

To guarantee repeatability of acquisition set, and to have some more fixed parameters for limb configuration, we realized a thermoplastic mask (see Fig. 3), modelled for the specific case-test: this mask is made of a sheet of Efficast™, produced by Orfit®, which is used to fix knee articulation in a static posture, useful for all acquisitions.

![Fig.3 The mask to fix the knee.](image)

We tested experimentally the different methods of acquisition, analysing four patients with amputated limb below the knee; the patients were three men and a woman, from 25 to 40 years old, with a stump length of approximately 10 cm below the tibiae plate.

### 4. ACQUISITION AND RECONSTRUCTION OF THE STUMP GEOMETRY

This paragraph describes procedures and results obtained in the acquisition and reconstruction of stump geometry using all methods previously identified (see Fig.4). In relation to 3D geometric model reconstruction, we highlights that only tasselled surfaces (in the .stl format) have been obtained. In the following parts, we describe, first, the three different measurement techniques applied to the mentioned test cases, and then the main features of the geometric models reconstructed.

![Fig.4 Main steps of the digital model reconstruction](image)
4.1 Laser scanning

Non contact laser scanning may be a significant method to control the modifications of lower limb’s morphology, especially for the global limb conformation and skin condition, and this is necessary both at the start of prosthesis design and throughout patient’s life, to register further residual limb assessments and realize the necessary functional socket variations.

This methodology allows:
- to acquire, in a not invasive and dangerous way for the patient, the morphology of the stump;
- to have digital models which permit an easy evaluation of the assessments and/or alteration suffered by limb, for the normal post-surgical course and for skin’s abrasions and blisters. Moreover, digital models permit to detect the variations of shape and volume due to incorrect pressures at the limb-socket interface, evidencing also the possible changes depending on the posture or on the health conditions of the patient.

We used a typical Reverse Engineering tool, the laser scanner Minolta Vivid 9i, which is normally used for industrial applications, equipped with a middle lens having \( f = 1.4 \) mm. In this application we adopted the following settings:
- in order to limit as much as possible the acquisition time and to avoid muscular contractions, a single stripe light is scanned, applying only a filter for noise reduction and edges’ control;
- the depth of view is about 850mm (±100mm) to keep measurements into the standard instrument’s field and guarantee laser acquisition accuracy.

We defined an operative procedure for the laser acquisition which includes:
- a setup which ensures a good patient’s comfort;
- a scanning modality to have a short acquisition time;
- a level of accuracy to respect the fixed parameters;
- a level of completeness of the 3D digital model of the external stump surface, to define the different level of detail to be used in the different process steps and applications.

The 3D digital models made of tasselled surfaces have been reconstructed with a good precision, being the standard deviation of the models’ alignments of about 1mm (±0.2mm). We accept this tolerance according to socket’s operability: if the value is maximum, it will be balanced by the liner deformability, made of polymeric material, and if the value is minimum it will be compensated by the use of cotton socks which are worn upon the socket.

The difficulties of the 3D digital reconstruction are connected to the stump deformability due to muscular contractions occurring during acquisition and with skin artefacts following the amputation surgery; in this context, the landmarks’ definition and their positioning on stump are a crucial step.

We used a procedure based on Davis’ protocol, with a personalization according to lower limb amputation; femoral epicondyles, patella plate and the tibia apex define the stump’s length. In addition, other reference points have been considered, projecting the principal points into the sagittal and frontal planes, in order to create a grid for scans’ alignment (Fig. 5-6-7).

The principal problems occurred during acquisition are caused by noise generated by downy skin on the stump, and by uncontrolled muscular contractions especially in the fleshy parts at the stump’s apex (Fig. 8-9). They have been corrected verifying in each case that mesh deviation from the original remains on the fixed tolerance limits. In the same way, we reduced mesh triangulation to keep the digital model the best handled as possible without losing surface details.

Fig.5 Test4 – landmarks on stump  
Fig.6 laser digital reconstruction  
Fig.7 mesh detail (253200 triangles)
4.2 CT acquisition

Computer Tomography (CT) medical imaging is a diagnostic technique which examines the inner body structures through two-dimensional X-ray images, taken around a single axis, each slice having a determined thickness. CT scanning can reveal a detailed image of soft-tissue and other body parts, with different grey level. This technology is particularly used to detect bones’ disease after a traumatic incident, according to the good contrast between bones and the X rays; on the other side, it is an invasive medical diagnostic technique, which must be used with care.

For our activities, we employed the PICKER PQ 5000 by Philips-Marconi Medical System, into the Radiology Division of Ospedale Gaetano Pini, in Milan. Also in this case, we have four test cases, three men and a woman, having a stump length under the tibia plate of about 10cm. We adopted a slice thickness of 5mm to provide a minimum X-ray exposure, according to an accurate bone reconstruction. The DICOM standard format for the 2D images has the following parameters: bitmap dimension 512x512 pixel, 16 bit, pixel size=0.3/0.5mm, DFOV of 20x20 cm. The images were transferred from the medical workstation to a personal computer to be processed. During CT acquisition markers were used according to laser acquisition, as shown in Fig.10-11.

The 2D slices acquired from CT were analyzed using the software Mimics 9.01 by Materialize28; we adopted the following procedure:

- a selection of points has been done through a segmentation mask, using thresholding and region growing action to separate the region of interest;
- a manual editing has been used in order to erase artefacts,
- the digital polygonal models of the skin and bones have been calculated.
The resulting digital models have good quality in the 3D bone reconstruction, for which the thickness slice is adequate to obtain the necessary detail; the external surface has less definition referred to anatomic characteristics, such as cicatrix and abrasions, which have great importance in the socket-limb interaction (Fig.12-13-14-15).

As far as CT acquisitions are concerned, we adopted the same limb support employed during laser acquisition, in order to keep the residual limb fixed in the delivered position; this support was easily integrated into the standard CT acquisition equipment tools.

4.3 MRI acquisition.

Magnetic Resonance Imaging (MRI) is a non-invasive high resolution technology which acquires multi-dimensional data not only in body transversal plane, like CT, but even in sagittal and frontal planes. MRI can acquire slices with high resolution and differentiation between soft and cartilage tissues, but at the moment it is very expensive for normal research diagnostic and requires a long scanning time to acquire the whole stump, and moreover it may be affected by artefacts due to muscular movements.

In our test cases, we utilized a GE Medical Systems, 1.5 Tesla Signa Excite, at the Centro Diagnostico Italiano in Milan. We set the test parameters at these values: slices of 20x20 cm, 256x256 pixel, pixel size= 0.78/0.82mm, obtained using a sequence with Repetition Time= 38/50, Echo Time=1,5/1,6, Flip Angle= 30° (Fig.16-17).

MRI acquisitions concerned only three patients, because the femoral metal sheet of one amputee does not permit this data diagnostic system.
Some problems occurred using our supporting device, whose integration with the MRI apparatus used for lower limb scanning was difficult; the magnetic knee bore has diameter of only $\Phi = 40\text{cm}$ and requires horizontal leg positioning and our system needs a little more volume to be totally performing. We do not try open bore magnets because their magnetic field is less strong and produces a limited spatial resolution.

MRI slices were affected by noise, which needed a pre-processing filtering to improve definition, but losing in detail quality; the reconstructed digital model has been recognized quite similar to the laser model, with a less accurate and detailed surface (Fig.18-19).

5. COMPARISON OF 3D DIGITAL MODELS

In this paragraph we discuss the geometric models reconstructed by using the different methods illustrated. First, we analyse the quality of the external surfaces and then the complete model.

5.1 Surface model definition.

The comparison between the reconstructed 3D digital models of the lower limb surface shows:

- the laser model has a high quality in morphological detail, necessary for the following studies of limb/socket interface stresses (Fig.20-21);
the CT models have a less skin quality, depending on slice thickness, but have a good correspondence with the laser model using the same reference markers typology (lead shot);

the MRI models have some volume differences due to the little difference in posture during stump acquisition; they have requested some post-processing editing to control noise and roughness, but they present a sufficiently detailed surface (Fig.22-23).

In conclusion, we notice that the 3D digital model reconstructed with a Reverse Engineering system such a laser scanner presents a better correspondence with the real skin surface: it shows all the “abnormalities” due to amputation, stump conditions and socket’s possible interactions.

We use this model as reference for the complete 3D reconstructed model.

5.2 3d complete model.

To obtain the 3D digital integrated stump, together with the external surface and the inner bone structure, we aligned the different model into the same reference global system, using the software Geomagic Studio 7.0\textsuperscript{29} to verify the differences. We obtained a good models’ positioning, especially in the anterior limb part, corresponding to the tibiae, while variations are located in residual limb apex, where there are the soft tissues (Fig.24-25-26).
6. CONCLUSIONS AND FUTURE WORKS

In this paper we first present an innovative approach to prosthesis socket design and then discuss methods to reconstruct 3D geometric model of the stump. For this purpose, RE, CT and MRI have been considered; we develop some test cases to identify the best methodology to reconstruct geometric model. The results obtained have demonstrated that the integration of RE for the external surface and medical imaging (CT or MRI) for internal skeletal structure permits to obtain a high quality digital model for prosthesis socket design, and reduces errors of current measurement operations and traditional pre-casting process.

Further developments will concern:
- the comparison between the digital model obtained and the one acquired from the plaster cast of the same residual limb through the traditional approach, to notice volume and detail variations;
- design of an apparatus which fitted the stump supporting device, to improve a better acquisition in reduced time for the proposed technologies, with attention for MRI specific application;
- simulations of interactions between socket and stump, to analyze stresses during moving and to obtain important feedback for socket design and modification.

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